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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,484	12/03/2003	Ramon A. Torres	TORRES=1B	3990

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,484	TORRES, RAMON A.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/3/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

The current status of application no. 09/475,989, i.e. "now US Patent 6,696,063" should be included in the first sentence of the specification.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 55. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims encompass administering a "functional derivative, fragment, variant, analog or salt" of human growth hormone releasing hormone (hGHRH). The specification does not clearly define what structural features would be required by the claimed hGHRH derivations to retain hGHRH biological activity. In addition, it cannot be determined what is intended by "functional derivative". Is it intended that this derivative possess a different function from hGHRH?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to methods of treating HADDS or regional accumulation of adipose tissue by administering hGHRH or a "functional derivative, fragment, variant or analog" thereof, which retains activity of hGHRH. The claims do not require that the substance, variant or the derivative of the variant possess any particular distinguishing feature or conserved structure.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a functional characteristic attributed to the "biological activity" of hGHRH. However, there is no identification of any particular portion of hGHRH that must be present in the instantly claimed hGHRH derivations. However, a definition by function alone "does not suffice, to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lily*, 119 F.3 at 1568, 43 USPQ2d at 1406. Accordingly, in the absence of

sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of hGHRH derivatives claimed. Although it is recognized that the prior art recognizes a number of hGHRH derivatives, as evidenced from page 44 of the instant disclosure, there is no support for the genus of hGHRH derivatives claimed that retain the biological activity of hGHRH.

Therefore, only isolated hGHRH and hGHRH art-recognized derivatives, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. (Metabolism, Clinical and Experimental. 1996; 45 (6): 738-746).

The claims are drawn to methods of treating HADDS or regional accumulation of adipose tissue by administering hGHRH or a derivative thereof.

Wilson et al. teach administering hGHRH to HIV-infected individuals, see "Subjects and Methods" bridging pages 738-740. Although Wilson et al. do not mention "HADDS" or diminishment of redistributed fat, the patient population, method steps and ingredients administered by Wilson et al. are indistinguishable from those instantly claimed. Therefore, it is determined that diminishment of redistributed fat in HIV-infected individuals is an inherent property of hGHRH. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of P. cepacia. A U.S. patent to Dart disclosed inoculation using P. cepacia type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.). "[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nontheless inherent in it." See *In re Oelrich*, 666 F.2d at 581. Additionally, the courts have determined that "[I]nherency is not necessarily coterminus with the knowledge of those of ordinary skill in the art." See *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). That is, it need not have been appreciated or recognized that the prior art reference inherently discloses the same invention for the reference to be

anticipatory. See *Mehl/Biophile Int'l Corp. v. Milgraum* 192 F.3d 1362, 1365 (Fed. Cir. 1999); *Atlas Power Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Draper et al. (US 5,767,124).

Draper et al. anticipate administering growth hormone secretagogues (Forms I and IV in particular) to obese and HIV-infected individuals, see column 15, line 66 to column 17, line 34. Although Draper et al. do not mention "HADDS" or diminishment of redistributed fat, the method steps, population and ingredients administered are indistinguishable from those instantly claimed for reasons discussed above.

Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mugica (US 5,120,713) or, in the alternative, Bowers et al. (US 5,663,146).

The claims are drawn to treating the pathological accumulation of adipose tissue in specific regions by administering hGHRH or a derivative thereof.

Mugica or, in the alternative, Bowers et al. anticipate administering hGHRH or derivatives, respectively, to obese individuals to diminish fat tissue, see claim 9 for example in Mugica or alternatively, column 4, lines 54-59 of Bowers et al. The diminishment of adipose tissue in any subject by administering hGHRH or a hGHRH derivative, as taught by Mugica or, alternatively, Browers et al., anticipates these claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Primary Examiner
Art Unit 1648